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Study Finds Supplements Contain Contaminants

By GARDINER HARRIS

Nearly all of the herbal dietary supplements tested in a Congressional investigation contained trace amounts of lead and other contaminants, and some supplement sellers made illegal claims that their products can cure cancer and other diseases, investigators found.

The levels of heavy metals — including mercury, cadmium and arsenic — did not exceed thresholds considered dangerous, the investigators found. However, 16 of the 40 supplements tested contained pesticide residues that appeared to exceed legal limits, the investigators found. In some cases, the government has not set allowable levels of these pesticides because of a paucity of scientific research.

Investigators found at least nine products that made apparently illegal health claims, including a product containing ginkgo biloba that was labeled as a treatment for Alzheimer's disease and a product containing ginseng labeled as a treatment to prevent diabetes and cancer. They also described a salesperson at a supplement specialty store who claimed that a garlic supplement could be taken instead of blood pressure medication.

Any product that claims to treat, cure, prevent or mitigate a disease is considered a drug and must go through strict regulatory reviews.

The report, which was prepared by the Government Accountability Office, was provided to The New York Times and will be made public at a Senate hearing on Wednesday. Its release comes two weeks before the Senate is scheduled to begin debate on a landmark food safety bill that is expected to substantially increase the federal government's authority over food manufacturers.

But it is uncertain how tough the bill will be on supplement manufacturers, and it has been the subject of fierce lobbying. Capitol Hill staff members familiar with the process said the bill was unlikely to include provisions opposed by supplement manufacturers.

Dr. Joshua M. Sharfstein, principal deputy commissioner of the Food and Drug Administration, said in an interview that he was not concerned about the safety of the supplements tested by the G.A.O. investigators. But Dr. Sharfstein noted that the agency had recently announced a recall of Vita Breath, a dietary supplement that it said might contain hazardous levels of lead.

Steve Mister, president of the Council for Responsible Nutrition, a trade association representing the dietary supplement industry, said it was not surprising that herbal supplements contained trace amounts of heavy metals, because these are routinely found in soil and plants. "I don't think this should be of concern to consumers," Mr. Mister said.

Senator Herb Kohl, a Wisconsin Democrat who will preside over Wednesday's hearing of the Senate Special Committee on Aging, said that while improvements had been made in recent years in the oversight of supplements, "the F.D.A. needs the authority and tools to ensure that dietary supplements are as safe and effective as is widely perceived by the Americans who take them."

Among the witnesses at the hearing will be Dr. Tod Cooperman, president of ConsumerLab.com, a company that has tested over 2,000 dietary supplements made by more than 300 manufacturers and has found that one in four have quality problems. According to Dr. Cooperman's written testimony, the most common problems are supplements that lack adequate quantities of the indicated ingredients and those contaminated with heavy metals.

Travis T. Tygart, chief executive of the United States Anti-Doping Agency, wrote a letter to the committee saying that some athletes have been rendered ineligible for international competitions because they took supplements that contained steroids not listed on the products' labels. There are thousands of supplements available for sale that contain steroids or other harmful ingredients, he wrote.

"The F.D.A. is operating in a regulatory environment that is simply too burdensome to allow for effective post-market regulation of these products," Mr. Tygart wrote.

Half of the nation's adult population takes vitamin supplements regularly, and about a quarter take herbal supplements at least occasionally. Annual sales are about \$25 billion a year, and the growing popularity has led to an increasing number of imported supplements spiked with illegal drugs.

In 1994, Congress passed legislation that allowed supplement makers to sell products without first getting approval from the F.D.A. for their ingredients or for basic health claims. But scientific organizations have warned repeatedly since then that the F.D.A. should do more to ensure that the supplements are safe and that their health claims are substantiated.

In recent years, a vast majority of supplement suppliers have located overseas - principally in China. Nearly

all of the vitamin C and many other supplements consumed in the United States are made from ingredients made in Chinese plants. Those plants are almost never inspected by the F.D.A. because the agency is not required to do so, has little money to do so and does not view the plants as particularly risky.

Mr. Mister said supplement sellers tested ingredients before using them, but he agreed that testing could not ensure quality. He called on Congress to provide the F.D.A. with more money to inspect foreign and domestic supplement plants. "I think you'll see more and more inspections," Mr. Mister said.

He said that a few companies made illegal health claims for their supplements, but that the industry was trying to police those. "I occasionally see these late-night commercials with health claims that make my blood boil," he said.

Dr. Sharfstein said the F.D.A. had increased enforcement actions against supplements spiked with prescription drugs like Viagra. And he said the agency had taken action against supplement makers that made broad health claims. "We don't want people to think they're treating a disease with something that hasn't been proven to do that," he said.

The food safety bill expected to be introduced next month in the Senate is likely to mandate that supplement makers register annually with the F.D.A. and allow the agency to recall supplements suspected of being dangerous.

But a House provision that would require manufacturers to create plans to safely manufacture their products and a proposal made in February by Senators John McCain, Republican of Arizona, and Byron L. Dorgan, Democrat of North Dakota, to restrict supplements to ingredients approved by the F.D.A. will not be included, staff members said.